IN-BRIEF

Use of Rapid Toxicology Screening Tools in Medical Examiner/Coroner Offices

"We sit at the intersection of public health and law enforcement. Reliable in-house toxicology testing, even when not used to complete and sign death certificates, offers timely information for the decedent’s family, which is very valuable for them.”
—Dr. Richard Harruff, Chief Medical Examiner, King County Medical Examiner's Office

Background

All medical examiner/coroner (ME/C) offices must make difficult decisions when allocating resources for timely, complete medicolegal death investigations. In some cases, toxicological analysis of a decedent’s biological specimens (e.g., blood, urine, tissue) can help determine cause and manner of death. A comprehensive toxicology work-up plays a key role in cases where an ME/C may suspect a drug-related death due to substances found with the decedent at the time of death, their medical history and presentation, age, or additional information provided by family or acquaintances. Offices may leverage an in-house laboratory, state or local crime laboratory, or private contracted laboratory for their testing needs.

Long turnaround times for comprehensive, confirmatory toxicology testing may delay the death certification process. Although the 2017 National Forensic Laboratory Information System (NFLIS) Medical Examiner/Coroner Office Survey reports that average turnaround time to complete a case is 31 days, this figure includes cases with and without toxicology testing. Anecdotal evidence indicates that death certifications may be delayed weeks or longer because of toxicology testing, and accreditation requirements illustrate the potential ranges of toxicology testing windows. Both National Association of Medical Examiner (NAME) and the International Association of Medical Examiners and Coroners (IACME) consider 90% of toxicology

Objectives

► Identify potential opportunities for use of rapid in-house toxicology screening tools in ME/C offices, based on practitioner feedback
► Discuss how these immunoassay-based tools can provide timely information to support death investigations and public health surveillance
► Outline the realities and limitations of current rapid toxicology screening tools in ME/C offices

Rapid Toxicology Screening as a Potential Tool for the ME/C Office

The ME/C community has started to look to a variety of tools and approaches to help them effectively deal with increasing casework and limited personnel. Rapid screening techniques may be used during external examinations or at autopsy, followed by comprehensive toxicological testing to verify positive screening results and to streamline the process of death investigation. Although screening techniques in the toxicology laboratory may include sophisticated instruments such as gas chromatography/mass spectrometry, liquid chromatography/mass spectrometry, or high-resolution mass spectrometry systems, this brief focuses on potential opportunities for simpler, lower-cost toxicology screening that can be used by ME/C offices, mostly in the form of immunoassay screening to inform the investigation. Most diagnostic immunoassays in in ME/C offices are used for urine, in the form of inexpensive dipsticks, cups, or strips that can detect one or more drugs or drug classes. These products typically cost between $5-10 for a single use assay and can be read in less than five minutes. Biochip assays using blood are used in toxicology laboratories and can be leveraged by ME/C offices; these devices may cost tens of thousands of dollars in addition to regular consumable costs. While biochip assays can detect more drugs and drug classes in one sample, they require a longer test time (roughly 20 minutes). These screening techniques can be used in a variety of ways to alleviate backlogs, help offices make informed decisions, and identify useful information during a death investigation. However, despite the advantages, the sensitivity, specificity, and effectiveness of these tool are limited, constraining their use in casework.⁶

Informed by interviews of ME/C offices, this brief captures potential opportunities and implementation strategies for rapid toxicology screening tools.

Potential Opportunities for Screening Tools*

- Inform the death certification process and pending case backlogs
- Inform ME/C offices during the investigative stage
- Provide timely information for external stakeholders, including family and public health and public safety communities
- Monitor drug trends in near real-time and inform budget needs

Realities of Screening Tools

- Limited specificity of screening tools: follow-up comprehensive toxicology screening and testing is necessary
- Lack of alignment with current products and ME/C screening needs; there is opportunity for growth
- Limited return on investment in well-resourced ME/C offices

*As screening tools, these should be used alongside, not in place of, traditional toxicology workflows.

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Potential Opportunities for Rapid Toxicology Screening Tools

Screening tools may be used in multiple applications in an ME/C office. Depending on the office, screening results may be included in reports, but with significant safeguards (e.g., details on a death certificate are amended if comprehensive toxicity workups disagree with screening results). However, screening tools can provide investigative intelligence, streamline workflows, and inform decisions regarding resource allocations. The purpose of screening tools is to help triage cases rather than replace the use of laboratory-based toxicology confirmation testing, and they may be used for many decisions as summarized below.

Inform the Death Certification Process and Pending Case Backlogs

When a drug-related death is suspected during a medicolegal death investigation, the ME/C office will order toxicology testing to identify whether a drug was present in the decedent to help determine if a substance caused or contributed to the cause of death. Interviewees indicated that this testing may take roughly 10 weeks or longer, depending on the caseload of the laboratory executing the tests. Death certifiers, therefore, must find strategies to either work with the delays or find ways to reduce delays. The increase in time for completion of cause of death on a death certificate has numerous downstream effects for investigations or families of decedents. Implementing rapid toxicology screening techniques at the ME/C office in addition to traditional laboratory-based screening and confirmation testing helped the King County Medical Examiner’s Office reduce death certification times while dealing with the realities of long comprehensive toxicology turnaround times (as shown on pages 6–7).

Inform ME/C Offices During the Investigative Stage

Across large and small ME/C offices, allocating limited resources is a key challenge. The National Association of Medical Examiners (NAME) recommends that any suspected drug-related death undergo a full autopsy and toxicology workup; however, personnel and funding constraints may limit offices to conducting external examinations. In some cases, no examination of the remains is conducted beyond examination at the scene. Medicolegal death investigation personnel face the reality of allocating autopsies and toxicology testing where they may provide the most value. Resource allocation inherently carries risk: offices may miss opportunities where autopsies reveal key insights that might suggest that factors other than drugs may have contributed to a suspected overdose case. ME/C offices often rely on multiple approaches to mitigate this risk in making resource allocations. These may include “risk analysis” calculators or tools like rapid toxicology screening techniques to provide a presumptive or “diagnostic” perspective. The NAME position paper, Recommendations for the Investigation, Diagnosis, and Certification of Deaths Related to Opioid and Other Drugs, suggests that pathologists consider information like hospital antemortem drug screens in their evaluation, and notes that some forensic offices may employ urine screening tools to assess cases for the presence of drugs. During this investigative stage, these screening products may be used in many different approaches to help make decisions.

External Examination with Toxicology Screening

ME/C offices may use rapid screening, often with urine dipsticks, as a screening for cases where overwhelming evidence points to a drug-related death: for example, the decedent presents with evidence of drug usage (paraphernalia or expressed drug use history), no other relevant medical history, and no evidence of foul play. This toxicological screen is taken during an external examination; if the urine screen suggests potential drug use that led to an overdose, the ME/C office then proceeds with a comprehensive toxicology work-up but does not proceed with autopsy. This approach does not align with NAME’s recommendation to conduct autopsies for each suspected drug overdose case and may not enable offices to capture the full sequelae of drug-related death complications. Without an autopsy, investigators may miss important details that may suggest the cause and mechanism of death, which is valuable not only to the case but to public health entities. However, this may be a necessary strategy to deal with large caseloads and sparse resources. This approach may also be used in cases where the decedent has a religious exemption to autopsy.

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Triage to Inform Testing During an Autopsy

Although screening tools may help relieve ME/C offices of autopsy burdens associated with drug-related deaths, some offices may proceed with autopsies for suspected drug-related deaths in accordance with NAME recommendations. These offices can use urine screening as a triage tool to help inform additional tests during the autopsy. For example, if a urine screen on a suspected drug-related death is negative, the ME/C may consider conducting additional tests or collecting additional specimens outside of the standard examination, such as additional sections of vital organs, histology testing, or metabolic and genetic testing. Results of these screening tests are not shared on reports and do not impact whether comprehensive toxicology testing is ordered, but they may help suggest potential testing directions that could provide value to ME/C offices and public health.

Screening for Potential Drug-Related Deaths

Rapid toxicology screening tools may help ME/C offices identify instances of drug-related deaths in cases where a drug-related death is not entirely apparent. Comprehensive toxicology testing is not part of every death investigation: it might not be used in cases where there is no medical history or anecdotal evidence that may suggest that the individual is a drug user. In this case, a negative screen could rule out possible intoxication and may be used to certify death as a natural cause without an autopsy. Positive screening results may also suggest the need for further toxicology testing and may also help in cases where they are considering whether drugs may have played a role in the individual’s death. ME/C offices must be diligent in ensuring execution of appropriate death investigation procedures while being mindful of realistic resource limitations. Toxicology screening tools can help these offices make informed decisions about allocating these resources.

Providing Timely Information to Stakeholders in Death Investigation

ME/C offices must interact with a variety of stakeholders during a death investigation. Stakeholders can range from law enforcement officers, public health and public safety communities to the family of the decedent. Although the type of information required by each stakeholder group may vary, all stakeholders stand to benefit from receiving accurate information as quickly as possible. In the case of law enforcement officers, more rapid delivery of information ensures they can conduct their investigation in an accurate and timely fashion. Additionally, law enforcement officers can use insights from individual cases to improve assumptions and situational awareness for other parallel or subsequent investigations (e.g., new opioid resulting in a spike in drug-related deaths in an area).

In addition to law enforcement officers, the family of a decedent has their own set of requirements as stakeholders. The family of a decedent needs a death certificate, which helps them close out the individual’s accounts, process insurance claims, and ultimately helps them process their loss emotionally. ME/C offices may “fast-track” preliminary death certificates using data from rapid toxicology screening tools (and revise at a later stage if changes are needed after the comprehensive toxicology workup), which provides closure on a shorter timescale than waiting for traditional toxicological testing. Even if this information is not used for formal ME/C reports, it can provide important information to the families.

Monitoring Drug Trends in Near Real-Time and Informing Budget Needs

The information age has ushered in a new era for how communities approach the collection and use of data to inform decisions. This reality has become especially true for the members of the ME/C community and the demand for real-time data on deaths, especially considering extreme circumstances like natural disasters, the COVID-19 pandemic, and the opioids epidemic. Rapid toxicology screening tools may help capture data that inform ME/C offices of drug trends. Multiple experts in the ME/C community commented on how these rapid tests could be used to provide informed numbers of drug-related deaths quickly. Near real-time data are not only valuable to the public and the public health community, but also help inform ME/C offices on current and future caseloads. These data may be used to understand resource needs for budgets and staffing.

Needs for near-real-time drug surveillance drove King County Medical Examiner’s Office in Washington State to pilot toxicology screening techniques to collect useful data in suspected cases of drug-related deaths. The office enters toxicology screening results from blood or urine tests in their Overdose Surveillance Database, and regularly disseminates this information to a network of 17 federal, state, and local agencies across law enforcement and public health.
These rapid tests can also help illuminate research paths that can result in findings that have significant utility to the ME/C community. Specifically, many of the improvements revolved around the comprehensiveness of the investigation process and ensuring there are no misclassifications of cause of death. Presumptive testing may help reduce the number of drug-related deaths overlooked each year by providing a qualitative screen to suggest further testing is required. Data comparing toxicology screening results to confirmatory toxicology workups may also help improve upon current presumptive techniques in different situations (e.g., blood and urine samples from decomposed decedents). For example, researchers from the John Jay College of Criminal Justice (The City University of New York), the Office of the Chief Medical Examiner, San Francisco, and University of California evaluated the Alere iCup DX 14 point-of-care urine screen test results against comprehensive toxicology testing results for postmortem urine samples. The study noted iCup sensitivity across 14 drug classes ranged from 66% to 100%, and specificity for each class ranged from 89% to 100%.8

The potential for rapid test application is not exclusive to the products in the current marketplace. The need to establish new, more comprehensive testing modalities that enable robust measurement of postmortem fluid samples has been a growing area of research. One example of related National Institute of Justice-supported efforts is the development of a microfluidic device that enables the field screening of cocaine and methamphetamine in oral fluid from Florida International University (NIJ Award 2013-DN-BX-K032). Researchers are also looking to create rapid and robust testing protocols for postmortem body fluid samples, using methods like liquid chromatography/mass spectrometer/mass spectrometer (2006-DB-BX-K015) and solid phase microextraction (2003-IJ-CX-K002). There is potential to develop these technologies further and move them to the field and the ME/C space to encourage postmortem testing for a myriad of drugs.

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The King County Medical Examiner’s Office Uses Rapid Testing Alongside Comprehensive Toxicology Testing to Decrease the Burden of Extended Turnaround Times.

Dr. Richard Harruff is the Chief Medical Examiner and Dr. Nicole Yarid is an Associate Medical Examiner for the King County Medical Examiner’s Office in Washington State.

The King County Medical Examiner’s Office has implemented rapid urine and blood toxicology screening in conjunction with comprehensive toxicology testing. Implementation of this technology was driven by a lack of up-to-date information on drug-related deaths; the state laboratory had an up to 8-month turnaround time for comprehensive toxicology results, and statewide drug death statistics were around two years old. To address these issues and move toward a goal of near real-time drug surveillance, the office researched the effectiveness of screening techniques to identify, and report probable overdose deaths and ultimately implemented this workflow to streamline death certification.

To prioritize cases as “probable overdoses” for rapid toxicology screening: the decedent must meet at least two conditions, shown below.9

For King County pathologists to consider a case as a “probable overdose,” at least two of these conditions should apply:

1. No alternative cause of death apparent/note of intent
2. Clinical symptoms of drug overdose described by investigator
3. Suspected illicit drug substance present/reported proximal drug use
4. Suspected illicit drug paraphernalia present
5. Prescription medication over-utilized
6. History of prior acute or illicit drug use (with overdose risk)
7. Valid hospital toxicology test result
8. Investigator/police report it as possible drug overdose, or other indication of overdose identified by medical examiner

Cases meeting these conditions are subject to in-house blood and urine testing from samples collected at autopsy. Blood samples are tested using an Evidence MultiSTAT (Randox®) automated immunoanalyzer, and urine samples are tested using One Step Detect Multi-Panel Forensic Test (DrugTestKitUSA®) urine cups. The office also collects and tests drug evidence from a death scene investigation using a TruNarc (Thermo Scientific) Raman spectrometer, a ResQ (Rigaku) Raman spectrometer, and a MX908 (908devices) portable mass spectrometer.10 If agreement between the two screening tests points to likelihood of acute drug toxicity, the death certificate is issued as an acute drug toxicity case. In addition to using these screening techniques within the ME/C office, the King County Medical Examiner’s Office also sends samples to the Washington State Patrol Laboratory for comprehensive toxicology screening and confirmation testing. Any discrepancies between the comprehensive work-up and screening results within the ME/C office are amended on the completed death certificate.

Medicolegal investigators in King County follow a series of steps for death certification in probable overdose cases:

1. Respond to death scene, collect evidence.
2. Conduct autopsy, with collection of blood, urine, other samples for toxicology testing.
3. Use method to prioritize cases of “probable overdoses” (see above).
4. Test urine or blood samples using rapid toxicology for cases meeting conditions of probable drug overdose.
5. Send samples to toxicology lab for confirmatory testing.
6. Issue death certificate as acute drug toxicity case if there is agreement in rapid tests.
7. Amend results based on confirmatory toxicology testing, if necessary, on completed death certificate.

King County’s process for identifying possible drug overdoses and streamlining death certification has proved to add value. During their initial study, 301 of 309 suspected overdose deaths that would have been delayed by confirmatory

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10 The companies and technologies detailed in this brief were used by King County Medical Examiner’s office. Neither DOJ, NIJ, nor FTOC endorse or advocate for any of these products.
toxicology testing were accurately certified based on results from the Randox blood tests, and only eight required removal of a drug from the final death certificate (all eight were correctly certified as overdose deaths). The Randox instrument can screen for 20 different drugs and drug classes, whereas the One Step urine cup is able to screen for 14 different drugs and drug classes, as screening tools, these tests do not cover the full range of possible drugs but can be used for some novel psychoactive substances. The Randox results from the blood test samples, relative to the ground truth measurements, had sensitivity ranging from 85% to 100%. The specificity of the tests ranged from 86% to 98%. During the study period, the interval between postmortem examination to certification of death because of overdose dropped from 75 days to 31 days. Based on these positive results and their strong collaborative relationship with the Washington State Patrol toxicology and crime laboratories, the King County Medical Examiner’s Office is continuing this practice and leveraging screening data for near real-time monitoring and drug surveillance.

Lessons Learned

- Collaboration across stakeholder groups is key for implementing new workflows. Buy-in from the Washington State Patrol enabled a successful and informative pilot study.
- Though screening techniques can be used to help streamline and make decisions, they should be used alongside (and not in place of) confirmatory toxicology testing.

Realities of Using Rapid Toxicology Tools in ME/C Offices

Although screening tools could play a role in multiple applications across workflows, they are not widely adopted by ME/Cs, or their use is experimental. Offices are often hesitant to implement screening tools into practice for numerous reasons, recognizing the technical limitations of these testing methods, gaps in currently available screening tools, and the varied return on investment.

Limited Scope of Presumptive Screening Tools

ME/C offices recognize the role of these tools as presumptive or “diagnostic” screening tools and are often hesitant to use them as anything beyond an informative, internal tool. As rapid screening tools, blood and urine immunoassays have limited sensitivity and specificity compared with confirmatory toxicology testing. Because of the threshold nature of the assay, these methods only provide the reliable, qualitative, binary data regarding whether a drug or drug class is present in the sample at or above a particular cutoff concentration. Although some blood immunoassay screens test for specific drugs, urine screening tools often are limited to drug classes, which lack the specificity recommended by the Centers for Disease Control and Preventions’ Vital Statistics Reporting Guidance.

Current NAME guidelines, outlined in the 2020 NAME position paper, Recommendations for the Investigation, Diagnosis, and Certification of Deaths Related to Opioid and Other Drugs, do not reference screening tools as means to handle large numbers of suspected drug deaths, and certain uses like screening in lieu of autopsy do not align with the NAME recommendation to conduct an autopsy on every suspected drug-related death. However, the guidance document suggests considering information like antemortem toxicology screening results (e.g., from hospital admission) and acknowledges that some offices may employ rapid urine screening tests to assess cases in the morgue. The paper notes that “screening tests alone offer generally incomplete evidence, are subject to false positives, and are thus inadequate for establishing a cause of death,” and recommends a comprehensive toxicological analysis to inform ME/C offices on controlled and illicit substances that may have contributed to

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12 The full test menu for the One Step Detect Multi Panel Forensic Test can be found at https://www.1stepdtx.com/product/multi-panel-forensic-test-cup-10-pack-2/

False negatives and false positives are realities of screening tools, and many offices feel uncomfortable using screening results on a death certificate without appropriate safeguards, even if they are pending. For example, King County Medical Examiner’s Office uses drug screening at autopsy, but in parallel, sends samples to the Washington State Patrol Laboratory for screening and confirmation. This allows for a more rapid death certification, and near real-time drug surveillance but also makes sure to confirm drug conclusions from the screening at autopsy.

**Lack of Alignment of Current Products to Fit ME/C Screening Needs**

Feedback from the ME/Cs routinely featured hesitancy concerning the current state of technology available in the rapid testing space. Compared to urine, blood provides the most accurate indication of drugs that may have contributed to an individual’s death and is typically available in decedents. Though preferred for screening, most blood immunoassay screening devices are large, expensive instruments (often tens of thousands of dollars, compared to single-use urine dipstick tests that cost a few dollars each) that may require training and maintenance. ME/Cs would find a dipstick-style test for blood valuable for screening purposes but are currently limited to urine-based dipstick tests. Development of inexpensive, simple blood tests may drive adoption in the future. Validation and pilot studies should be conducted anytime a new tool is implemented, and ME/C offices can lean on qualitative screening method validation recommendations for toxicology. In addition, ME/C offices must understand whether implementation of such screening tools impact current or future IACME and NAME office accreditation, in accordance with their guidelines.

**Limited Return on Investment in Some ME/C Offices**

As screening tools, use of these methods in ME/C workflows should be followed by comprehensive toxicology testing at a laboratory when appropriate. The return on investment, however, may not be high in well-resourced ME/C offices that have access to comprehensive toxicology resources with low turnaround times, whether in-house or contracted. In offices where resource allocation decisions are easier, these tools may be redundant and offer limited value.

**Summary**

ME/C offices need to make difficult resource allocation decisions, which are increasingly complicated by drug-related deaths from the opioids epidemic and continuous emerging drug threats, workforce shortages, and long turnaround times for toxicology testing and death certification. Rapid toxicology screening tools, such as urine and blood immunoassays, can provide useful information that may help inform pending death certifications, enlighten decisions during medicolegal death investigations (in accordance with office policies), and inform families of decedents, and other stakeholders interested in near real-time surveillance data. Despite experimentation with these methods by some ME/Cs, users agree that the technology is not mature enough or analytically reliable enough to replace traditional toxicology. Although an informative tool, these screening tests are presumptive and must be treated as such; their sensitivity and specificity are lower than comprehensive toxicology testing, and few on-market screening products fit the needs of ME/C offices. Implementation of these screening tools is not a “silver bullet” in addressing systemic workforce and resource issues. These tools may have more use in helping address long turnaround times in smaller, resource-challenged offices.

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